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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/089,994 | 07/02/2002 | Frank Luyten | | 5817 |

21559 7590 02/07/2005

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BOSTON, MA 02110

EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,994

Applicant(s)

LUYTEN ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 31-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' Preliminary Amendment, filed 4/3/02, has been entered. Claims 1-30 are cancelled. Claims 31-51 are added. Claims 31-51 are pending and under current examination.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 31-36 and 51, drawn to methods of positively identifying viable, expanded or passaged, committed, pluripotent skeletal precursor cells that have entered a post-natal differentiation pathway leading to skeletal or connective tissues.

Group II, claim(s) 37, drawn to methods for sorting or enriching precursor cells in cell culture *in vitro*.

Group III, claim(s) 38, drawn to a method for producing or repairing connective tissue in a mammal.

Group IV, claim(s) 39, drawn to a method of producing matrix.

Group V, claim(s) 40, drawn to a method of treatment by supplying precursor cells.

Group VI, claim(s) 41, drawn to a method for joint surface defect repair in a mammal.

Group VII, claim(s) 42, drawn to a method for enhancing the implantation of a prosthetic device in connective tissue.

Group VIII, claim(s) 43, drawn to a culture of isolated and expanded viable, differentiated, pluripotent precursor cells.

Group IX, claim(s) 44, 46, drawn to therapeutic compositions and a method of treating a patient by administration of the therapeutic composition.

Group X, claim(s) 45, drawn to an implant comprising differentiated, pluripotent precursor cells.

Group XI, claim(s) 47-50, drawn to a diagnostic for identifying *in vitro*, a positive marker of viable, committed pluripotent skeletal precursor cells.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features for the following reasons:

Unity of Invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product
- 2) A product and a process of use of said product
- 3) A product, a special process of manufacture of said product, and a process of use of said product
- 4) A process and an apparatus specially designed to carry out said process
- 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant invention.

37 CFR 1.475 (c) states that:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the

first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

Groups I-VII, IX and XI are drawn to distinct methods, which have a separate and materially different protocol. Each of these methods requires a specific protocol, and none are required for the function of the other. Groups VIII and X are drawn to distinct products, which require distinct materials and do not share the same inventive concept. Thus, it follows from the preceding analysis, that the claimed inventions listed in Groups I-XI do not relate to a single inventive concept because they lack the same or corresponding special technical feature.

The special technical feature of Group I is considered to be methods of positively identifying viable, expanded or passaged, committed, pluripotent skeletal precursor cells that have entered a post-natal differentiation pathway leading to skeletal or connective tissues.

The special technical feature of Group II is considered to be methods for sorting or enriching precursor cells in cell culture *in vitro*.

The special technical feature of Group III is considered to be a method for producing or repairing connective tissue in a mammal.

The special technical feature of Group IV is considered to be a method of producing matrix.

The special technical feature of Group V is considered to be a method of treatment by supplying precursor cells.

The special technical feature of Group VI is considered to be a method for joint surface defect repair in a mammal.

The special technical feature of Group VII is considered to be a method for enhancing the implantation of a prosthetic device in connective tissue.

The special technical feature of Group VIII is considered to be a culture of isolated and expanded viable, differentiated, pluripotent precursor cells.

The special technical feature of Group IX is considered to be therapeutic compositions and a method of treating a patient by administration of the therapeutic composition.

The special technical feature of Group X is considered to be an implant comprising differentiated, pluripotent precursor cells.

The special technical feature of Group XI is considered to be a diagnostic for identifying *in vitro*, a positive marker of viable, committed pluripotent skeletal precursor cells.

Accordingly, Groups I-XI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

twt
Thaian N. Ton
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Group 1632

Joe Winters
AUG 30